SPEAKER: Now one can ask, why would I wait if you've got a highly effective product and not use it in an earlier treatment regimen? And that's a legitimate question and a hypothesis that can be tested. Why not use your most highly effective drugs as early as you can? Keeping in mind that you've got to balance that between the treatment burden or cost or other adverse effects.

But in my experience, if I have a patient in whom I would be using amikacin, inhaled amikacin, from the beginning-- and that would be those patients who have cavitary disease-- I don't see a reason to subject them to six months of treatment before deciding to add the liposomal product. So in our clinic, we are using the liposomal product as we would have in all the patients in which we were previously using just inhaled amikacin. So we're using it in the upfront treatment of many of our patients.

Now I will mention that the approval of liposomal amikacin was a conditional approval based upon a microbiologic response. But the FDA's mandate is to evaluate drugs based on how they make a patient feel, function, or survive, and so they've expressed discomfort of whether microbiologic outcomes serve as a good surrogate for how a patient feels, functions, or survives. And additional work will have to be done to demonstrate that. In the meantime, my clinical experience has been that our patients have responded well to inhaled amikacin, and so we are continuing with our approach to those patients.